

## **REMARKS**

### **Species Restriction Requirement**

In response to the species restriction requirement set forth on pages 2-3 of the Office Action, the Applicants affirm the election of Species Group I. As indicated in the Office Action, claims 14-23 and 38-71 are directed to Species Group I. Claims 24-28 have been withdrawn as being directed to a non-elected Species Group II. The Applicant has chosen to cancel the withdrawn claims 24-28 from the subject application without prejudice for possible consideration in a continuing application.

### **Allowable Claims**

As set forth on page 4 of the Office Action, claims 16, 21-23, 40-45, 48, 67 and 71 have been objected to, but have been indicated as allowable if rewritten in independent form. To that end, the Applicant has rewritten each of the claims 16, 21-23, 40, 41, 43, 44, 48, 67 and 71 in independent form. Additionally, claim 42 depends from rewritten independent claim 41, and claim 45 depends from rewritten independent claim 44. Accordingly, the Applicant submits that claims 16, 21-23, 40-45, 48, 67 and 71 are now in condition for allowance.

### **Claim Rejections – 35 USC §102 and 103**

Claim 14 was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,486,505 to Morrison (hereafter “the ‘505 reference”). Claims 14, 15 and 18-20 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,797,909 to Michelson (hereafter “the ‘909 reference”). Claims 14, 15, 17, 18, 38, 39, 46, 47, 49-55, 60-66 and 68-70 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,042,582 to Ray

(hereafter “the ‘582 reference”). Claims 56-66 and 68-70 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,601,556 to Pisharodi (hereafter “the ‘556 reference”).

**Independent Claim 14 and Dependent Claims 15 and 17-20**

Independent claim 14 has been cancelled without prejudice for possible consideration in a continuing application. Dependent claims 15 and 18 have been amended to depend from rewritten independent claim 23, which has been indicated as allowable. As a result, dependent claims 15 and 17-20 depend either directly or indirectly from allowable rewritten independent claim 23 and are submitted to be patentable for at least the reasons supporting the patentability of rewritten independent claim 23. Accordingly, withdrawal of the rejection of dependent claims 15 and 17- 20 is respectfully requested.

**Independent Claim 38 and Dependent Claims 39, 45-47 and 49-55**

Independent claim 38 has been cancelled without prejudice for possible consideration in a continuing application. Dependent claims 39, 46, 47, 54 and 55 have been amended to depend from rewritten independent claim 44, which has been indicated as allowable. Additionally, dependent claim 51 has been amended to depend from rewritten independent claim 41, which has also been indicated as allowable. Dependent claims 39, 45-47, 49, 50, 54 and 55 depend either directly or indirectly from allowable rewritten independent claim 44 and are submitted to be patentable for at least the reasons supporting the patentability of rewritten independent claim 44. Similarly, dependent claims 51 and 52 depend either directly or indirectly from allowable rewritten independent claim 41 and are submitted to be patentable for at least the reasons supporting the patentability of rewritten independent claim 41. Accordingly, withdrawal of the rejection of dependent claims 39, 45-47, 49-52, 54 and 55 is respectfully requested.

Dependent claim 53 has been rewritten in independent form and is submitted to be patentable over the references of record for at least the following reasons. Rewritten dependent claim 53 recites, among other elements and features, a stem portion extending along a longitudinal axis and adapted for insertion within the intervertebral space, a transverse flange portion adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space, and a surgical instrument comprising a tubular sleeve sized to receive one or more surgical devices therethrough for advancement toward the intervertebral space, with the tubular sleeve being selectively and releasably engaged with the stem portion.

As set forth on page 4 of the Office Action, dependent claim 53 was rejected as being anticipated by the '582 reference to Ray. With regard to the '582 reference, even assuming arguendo that the insertion end portion 26 comprises an axial stem portion and the trailing end portion 24 comprises a transverse flange portion, there is no teaching that a tubular sleeve is "selectively and releasably engaged" with the stem portion, as recited in rewritten independent claim 53. As shown in Figures 6-9 of the '582 reference, although a retractor 100 is used to guide various instruments into engagement with the vertebrae, the retractor 100 is not in any way "selectively and releasably engaged" with the trailing end portion 24 of the spacer 14 (see Figure 6).

Indeed, there is no teaching or suggestion whatsoever that the retractor 100 even contacts the spacer 14, much less engages the spacer 14 in a selective and releasable manner. To the contrary, as discussed throughout the written description, the spacer 14 is inserted in a first later side portion of the intervertebral space (col. 6, ll. 57-62) with the retractor 100 inserted in a second later side portion of the intervertebral space (col. 7, ll. 14-16). Following preparation of

the adjacent vertebrae for receipt of an implant 500, the spacer 14 is removed and the retractor 100 is inserted in the portion of the intervertebral space previously occupied by the spacer 14 (col. 8, ll. 30-38). It should therefore be appreciated that the retractor 100 is not in any way “selectively and releasably engaged” with the spacer 14. For at least the forgoing reasons, the Applicant submits that rewritten independent claim 53 is patentable over the ‘582 reference to Ray. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 53.

**Independent Claim 56 and Dependent Claims 57-59**

Independent claim 56 and dependent claims 57-59 have been cancelled without prejudice for possible consideration in a continuing application.

**Independent Claim 60 and Dependent Claims 61-66 and 68-70**

Independent claim 60 and dependent claims 61 and 62 have been cancelled without prejudice for possible consideration in a continuing application. Dependent claim 63 has been rewritten in independent form and now recites: providing a device including an axial stem portion and a transverse flange portion, inserting the axial stem portion into an intervertebral space between the adjacent vertebrae, engaging the transverse flange portion against one of the adjacent vertebrae, and applying an axial force to the device and transmitting the axial force to the one of the adjacent vertebrae thereby resulting in axial displacement of the one of the adjacent vertebrae relative to the other vertebrae to reduce a spondylolisthesis condition.

As set forth on page 4 of the Office Action, dependent claim 63 was rejected as being anticipated by both the ‘582 reference to Ray and the ‘556 reference to Pisharodi. With regard to the ‘582 reference to Ray, even assuming arguendo that the insertion end portion 26 comprises

an axial stem portion and the trailing end portion 24 comprises a transverse flange portion, there is no teaching whatsoever that the disclosed device is used “to reduce a spondylolisthesis condition between the adjacent vertebrae”, as recited in rewritten independent claim 63. Specifically, the ‘582 reference fails to teach or even suggest the steps of engaging the trailing end portion 24 against one of the adjacent vertebrae and applying an axial force to the device “thereby resulting in axial displacement of the one of the adjacent vertebrae relative to the other of the adjacent vertebrae to reduce a spondylolisthesis condition between the adjacent vertebrae.” Albeit that the trailing end portion 24 of the device appears to abut one of the adjacent vertebrae (see Figure 5), there is no teaching or suggestion whatsoever that an axial force is applied to the device which results in relative axial displacement between the adjacent vertebrae to reduce a spondylolisthesis condition. For at least these reasons, rewritten independent claim 63 is submitted to be patentable over the ‘582 reference to Ray.

With regard to the ‘556 reference to Pisharodi, although this reference discloses an apparatus for reducing a spondylolisthesis reduction, the disclosed apparatus is not configured like the device recited in rewritten independent claim 63 and clearly does not satisfy all of the steps recited in independent claim 63. As illustrated in Figure 7 of the ‘556 reference, the reduction apparatus includes an end portion 12 that is split longitudinally into two side-by-side members 13, 14, one of which is movable relative to the other, and with each member 13, 14 including teeth 38 (Figure 1) for gripping the endplates of the adjacent vertebrae 33, 37. The members 13, 14 are inserted into the disc space between two misaligned vertebrae 33, 37 and one of the members 14 is moved relative to the other member 13 to reposition the adjacent vertebrae 33, 37 into alignment with one another.

With regard to the reduction device disclosed in the '556 reference, all of the correction force applied to the adjacent vertebrae 33, 37 is exerted via engagement of the teeth 38 against the vertebral endplates. Notably, the reduction device fails to disclose "a transverse flange portion", as recited in rewritten independent claim 63, and clearly fails to teach or suggest the recited step of "engaging the transverse flange portion against one of the adjacent vertebrae" to reduce a spondylolisthesis condition. The reduction device illustrated and described in the '556 reference is therefore configured different from the device recited in rewritten independent claim 63 and also operates and functions in a significantly different manner than that recited in independent claim 63. For at least these reasons, rewritten independent claim 63 is submitted to be patentable over the '556 reference to Pisharodi.

Based on the foregoing discussion, it is submitted that rewritten independent claim 63 is patentable over both the '582 reference to Ray and the '556 reference to Pisharodi. Accordingly, the Applicant respectfully requests withdrawal of the rejection of rewritten independent claim 63.

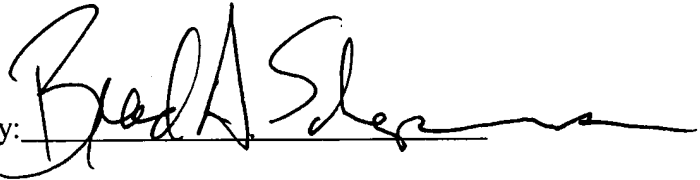
Dependent claims 64 and 68-70 have been amended to depend from rewritten independent claim 63. As a result, dependent claims 64, 66 and 68-70 depend either directly or indirectly from rewritten independent claim 63 and are submitted to be patentable for at least the reasons supporting the patentability of rewritten independent claim 63. Additionally, dependent claim 65 has been amended to depend from rewritten independent claim 67, which was indicated as being allowable. As a result, dependent claim 65 is submitted to be patentable for at least the reasons supporting the patentability of allowable rewritten independent claim 67. Accordingly, withdrawal of the rejection of dependent claims 64-66 and 68-70 is respectfully requested.

## CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 15-23, 39-55 and 63-71.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

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